

REMARKS

This paper is responsive to the Final Office Action mailed September 16, 2010, the response for which is due November 16, 2010. An amendment after final is appropriate where the Examiner changed the structure in the Final Rejection, admitting the earlier rejection was incorrect, while not permitting the Applicant a fair opportunity to address the new rejections. Moreover, the Examiner has made assumptions and read structure in to the prior art references that are inappropriate for an anticipation rejection. For the reasons set forth below, reconsideration is requested.

Rejections Under 35 U.S.C. §102

Claims 1-2, 4-12, 31-32 and 34-42 stand rejected under 35 U.S.C. §102(b) as being anticipated by Yoon (U.S. Patent No. 5,542,949). Claim 1 is set forth below:

1. An apparatus for forming a lumen from within an hollow body organ, comprising:
 - a tissue positioning device having a first opening in a first region for releasably adhering a first area of tissue and a second opening in a second region for releasably adhering a second area of tissue thereto, the first and second openings being separated by a septum;
 - at least one fastener housed within the device; and
 - wherein the septum being removable from between the first and second openings to allow the at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue via the fastener.

Yoon, upon which the first rejection of Claim 1 is based, purports to disclose a clip applying instrument with distal jaws spring biased apart, and surgical clips disposed in one or two clip magazines removably received in the instrument body. A handle is used to grasp and manipulate tissue when no clip is in the jaws, to advance clips into the jaws, and to cut tissue after clipping. [Abstract]. A major stated purpose of the Yoon device is to avoid repeated withdrawal of the instrument to load a new clip by utilizing an automatic clip feed mechanism. The device includes suction and irrigation tubes and a cutting instrument for cutting tissue.

It is black letter patent law that anticipation under 35 U.S.C. §102 requires "identity of invention:" the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1267, 20 USPQ2d 1746, 1748 (Fed.Cir. 1991); see also In re Spada , 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir. 1990) ("the reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it"). Here, the Office Action has failed to show where in Yoon the claimed feature because nowhere in the Yoon disclosure is there any teaching of the claimed tissue positioning device.

Applicant pointed out in its previous response that tube 86 does not come into contact with any tissue and Yoon fails to teach that it "releasably adher[es] a first area of tissue." The Office Action counters without support that "ports 86 and 88 are *capable* of releasably adhering to a first and second area of tissue. Applicant respectfully disagrees. A rejection for anticipation must be found within the four corners of the purported anticipatory reference, and Applicant is not responsible for rebutting the rejection until the Office Action has established a *prima facie* case of anticipation. There is nothing except the bald assertion of the examiner to support the proposition that Yoon's device can adhere tissue. Once the Office Action demonstrates that Yoon taught this feature, then it would be appropriate for Applicant to respond. The Office Action's contention that Applicant has not argued that the ports are "functionally incapable" of suctioning tissue is contrary to the law. First, the Office Action must establish that Yoon taught this feature, and *then* it is the responsibility of Applicant to rebut.

However, Applicant notes that it is Applicant's position that the holes in the Yoon device are too small to adhere tissue, which is often wavy and undulating and could not likely make sufficient contact with the ports to establish reliable adhesion. Further, the position of the ports on the receding surface would make it difficult, if not impossible, to

establish one surface contact and making a second surface contact of the same organ's tissue simply cannot be reliably predicted.

If the Office Action is relying on a specific teaching in Yoon to show that ports 84 and 86 are capable of adhering tissue, Applicant respectfully requests that the citation in Yoon be provided. If the Office Action is relying on inherency, Applicant respectfully requests that the Examiner provide evidence of record as set forth in MPEP §2131 that Stack's pleats necessarily form a tissue bridge:

when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

Thus, the evidence requested by Applicant must show that Yoon *necessarily*, and not potentially, could suction tissue. If no evidence is forthcoming, then the rejection cannot stand and must be withdrawn.

Claim 1 also calls for the first and second openings to be separated by a septum. The term "septum" has a well understood meaning in the art, and serves a well understood purpose. Anticipation rejections are not subject to manipulation of what the disclosed device could do if certain modifications were made, but rather is limited to what the purported reference actually teaches. Here, the Office Action contends that cutting member 223 and case 228 satisfy the limitation of the septum. But cutting member 223 cannot just be characterized as a septum without further explanation. Yoon does not assert that it serves any "septum-like" purpose, and the Office Action does not explain why the cutting member satisfies the septum limitation.

Also, there is no evidence of record that the cutter member 223 is "removable from between the first and second openings." That is, there is no evidence that the cutter member 223 ever achieves a position between the openings 86,88, so there is no evidence

that the cutting member is "removable **from between** the first and second openings." Again, the Office Action is not permitted to speculate on what the Yoon disclosure teaches, but must rely on the actual teachings found within the four corners of the Yoon reference in order to satisfy the requirements for a *prima facie* rejection for anticipation. Yoon is silent on where the cutting device is deployed with respect to the ports 86,88. Accordingly, the rejection based on Yoon must be withdrawn, or evidence of record presented that substantiates the positions taken by the Office Action but silent in Yoon.

The Office Action counters that the cutting members may be positioned between the jaws. However, the Claim calls for the septum to be between the tissue adhering regions, not the jaws. The "ports" are at the distal end of the jaws. There is no evidence provided that the cutting members extend to a position between the ports. Simply arguing that the cutting members may fall between the jaws is legally insufficient, since the cutting members may indeed extend between the jaws but not the ports. Therefore, the rejection is improper and inadequate on its face. Applicant respectfully requests that a the rejection be withdrawn and either a new rejection entered establishing with evidence of record that Yoon teaches a septum **separating** two tissue adhering areas, or passing the Claim to allowance.

Further, Claim 1 calls for at least one fastener to be deployed such that the first area of tissue is secured to the second area of tissue. The first area of tissue is what is adhered to the first opening, and the second area of tissue is adhered to the second opening. Although there is no evidence that Yoon's ports serve any purpose besides aspiration and evacuation of fluid, even if the ports did adhere tissue as the Office Action contends, there is no disclosure in Yoon that these two areas of tissue are then secured together by the clip of Yoon. Particularly since Yoon places his tubes 86,88 on the outside periphery of the device to permit irrigation and suction, and it would be impossible to then clip tissue adhered to the outside surfaces where tubes 86,88 are located with the device of Yoon. Thus, the rejection of Claim 1 based on Yoon must be withdrawn for this reason as well.

In addition, the Yoon device only discloses that tissue is cut with the cutter device **after** the clip is in place. Yoon states, "when it is desired to cut tissue after a clip has been applied," [Col. 6, lines 62-64] Thus, there is no teaching in Yoon of "the septum being removable from between the first and second openings **to allow** the at least one fastener to be deployed" Since the clip of Yoon is already deployed, the cutter cannot serve the claimed septum and there can be no anticipation for this independent reason. The Office Action counters that Yoon could be used in a manner different from its stated purpose, but the Yoon device cannot be operated as suggested by the Office Action. That is, the Yoon apparatus cannot advance the cutter with the staple still in place as proposed by the Office Action. Rather, the clip must be deployed before the cutting instrument can be deployed. Thus, the Office Action's proposed modification of the Yoon disclosure, while inappropriate for a §102 rejection, is also factually incorrect.

It is clear from the foregoing that Yoon does not present the required "identity of invention" that is required for a Section 102 rejection. Applicant has identified no less than six limitations of Claim 1 that is not found in Yoon, or that the Office Action has not established with the required evidence of record. As such, the rejection of Claim 1 based on Yoon is properly withdrawn.

As for Claim 6, the Office Action contends that a vacuum is created in the first and second regions (from Claim 5) and that the first and second regions are in fluid communication with a common channel. The Office Action cites to element 89, but this element is the inner hollow cylinder but is not in "fluid communication" with the two vacuum regions. There could be no vacuum applied in Yoon if there were fluid communication with the cylinder 89, and the whole purpose of the vacuum would be frustrated. Thus, Claim 6 is not anticipated for yet another independent reason.

Claim 31 is similar to Claim 1, and the remarks set forth above with respect to Claim 1 are repeated and incorporated by reference with respect to Claim 31. Applicant therefore requests that the rejection of Claim 31 also be withdrawn.

Claim 1 also stands secondarily rejected as anticipated by Adams et al., U.S. Patent No 6,585,144. Claim 1 calls for "an apparatus for forming a lumen from within a hollow body organ." The Office Action counters that Adams teaches "a stapler device." The first opening of Claim 1 is asserted to be the staple forming groove 19, and the second opening of Claim 1 is asserted to be the staple slits 34. Clearly these two structures cannot meet the claim limitations in order to satisfy the requirements for anticipation. First, how can the port where staples are emitted possibly have tissue adhered thereto? Applicant respectfully submits that the presence of the staple precludes any tissue from being adhered to the staple slit, and that there is no teaching in Adams that the staple forming groove 19 has tissue adhered thereto either.

The Office Action responds that "when the staples are fired, before being released the ports and the stapler and anvil surfaces of the stapling devices adheres to the first and second areas of tissue." Applicant respectfully requests where this is taught by Adams. If there is a passage that teaches this feature, Applicant respectfully requests its citation by page and line number. If the Office Action is not relying on an expressed teaching, and instead is relying on inherency, then Applicant respectfully requests that the Examiner provide evidence of record establishing that tissue would *necessarily* be adhered to the stapler and anvil surfaces as proposed by the Office Action. An anticipation rejection must be based on the teachings of the prior art, not on hypotheticals and possibilities. As it stands, the rejection does not make out a *prima facie* case of anticipation and cannot be sustained.

Also, there is no teaching in Adams that a first area of tissue is secured to a second area of tissue, and clearly not first area of tissue adhered to the staple groove and a second area adhered to the staple slit. There is nothing resembling this teaching in Adams, and the rejection while imaginative is not supported by the record.

The Office Action argues that the Adams teaches applying suction in a "region," but fails to show how a vacuum is applied to the staple groove or staple slit. The cited passage relied upon by the Office Action (C14, ll56-64), which is to a completely

different embodiment, fails to support the Office Action's argument because drawing tissue "between" the groove 19 and the slit 34 does not teach adhering tissue "to" the slit and groove. There is simply no support for an anticipation rejection, and the Office Action's own evidence not only supports Applicant's arguments but establish it in a conclusive manner.

The Office Action further contends that the "septum" is satisfied by Adams' staple retainer 623. It appears that the Office Action has misunderstood the purpose of the retainer, which stays in place during the stapling procedure than thus does not meet the limitations of Claim 1. Namely the retainer 623 of Adams is not "removable between the first and second openings to allow the at least one fastener to be deployed." Because the whole purpose of the retainer is to remain in place between the staple slit and staple groove while the staple is ejected, there is no teaching of the claimed invention and the rejection based on Adams is properly withdrawn.

Claim 5 calls for the first area of tissue and the second area of tissue to be adhered to the tissue positioning device via a vacuum. The only way this can be accomplished is if the staple groove and the staple slit have vacuum applied therein, since these are the only locations where the first and second areas of tissue are found according to the Office Action. But since there is no vacuum in the staple slit or groove 19,34, there is clearly not anticipation of Claim 5 based on Adams. As for Claim 6, there is no fluid channel in fluid communication with the staple slit and staple groove as required in Claim 6, so there can be no anticipation of Claim 6 as well. Clearly the retainer 623 is not "longitudinally positioned in the tissue positioning device," and the rejection of Claim 10 is also improper. Further, there is no disclosure in Adams that the retainer 623 abrades tissue or that it is even capable of abrading tissue, much less using "heat" as asserted by the Office Action. Without support for the rejection, the rejection cannot stand and is properly withdrawn.

Claim 31 is similar to Claim 1, and the arguments set forth above with respect to Claim 1 based on Adams are repeated and incorporated herein by reference with respect

to Claim 31. Based on the foregoing, it is clear that the rejections based on Adams and Yoon are improper and fail to establish a *prima facie* case of anticipation. Since all of the outstanding rejections are based on one of these two rejections, Applicant respectfully asserts that the claims as presented are now in condition for allowance.

Applicants respectfully submit that claims 1-12 and 31-42 are patentable over Yoon and Adams et al. and that all pending claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

The Commissioner is authorized to charge deposit account no. 06-2425 for any unforeseen fees arising from the filing of this paper.

Respectfully submitted,

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